

II. Remarks

A. Introduction

Reconsideration and allowance of the subject application are respectfully requested.

Claims 1, 2, 5 - 15, 17, and 23 - 28 are pending in the application. Claims 1, 25, and 28 are independent, with claim 28 being newly added. Support for new claim 28 may be found on page 11 in Example 1. No new matter has been introduced by way of this newly added claim.

B. Examiner Interview

The undersigned and the Applicants would like to thank Examiner Yu for the cordial telephonic interview of April 25, 2007. During the interview, the Examiner indicated that the Notice of Abandonment dated April 3, 2007, which the undersigned did not receive until April 25, 2007, was issued in error. The Examiner further communicated that the Abandonment of the Application will be withdrawn, especially in light of the fact that Applicant timely filed a Notice of Appeal on or before the period for responding to the Office Action dated March 28, 2006 had expired.

C. Request for Information Under 37 C.F.R. § 1.105

Applicant submits that the formula for Sencil products is the formula disclosed on page 11 in Example 1 of the instant Application. The formula for the Sencil product that was first sold in the United States in May of 2002 is

described in the attached letter dated April 24, 2007 (attached hereto as Exhibit A)—substantially the same formulation described in the Apex International Manufacturing Procedure document, attached hereto as Exhibit B. Applicant respectfully submits that he has now complied with the Examiner's request under 37 C.F.R. § 1.105.

D. The rejections under 35 U.S.C. § 103(a) should be withdrawn

Claims 1, 2, 5 - 15, 17, and 24 - 27 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over U.S. Patent No. 3,431,340 to George (hereinafter "George"), Derwent Acc. No. 1984-271531 (hereinafter "Soto"), U.S. Patent No. 3,825,563 to Arhens (hereinafter "Arhens"), U.S. Patent No. 5,047,232 to Kaplan (hereinafter "Kaplan"), and U.S. Patent No. 6,099,866 to Slimak (hereinafter "Slimak"), for the reasons set forth on pages 3 - 7 of the Office Action. Claim 23 also stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over George, Soto, Arhens, and Slimak, further in view of U.S. Patent No. 5,874,479 to Martin (hereinafter "Martin"), for the reasons set forth on page 7 of the Office Action. Applicant respectfully traverses these art rejections.

Applicant offers that none of the references cited above, alone or in combination, teach all the claim limitations of independent claims 1, 25, and 28. George teaches a composition comprising 35 - 65% by weight castor

oil and 35 - 65% by weight cod liver oil. See, col. 2, lines 1 - 4. George's preferred composition comprises 40% by weight castor oil and 60% by weight cod liver oil. In contrast, the compositions recited in independent claims 1, 25, and 28 consist of about 10% by weight cod liver oil and about 3% by weight castor oil. The Examiner herself admits that "George fails to teach the remaining components recited in claim 1." Applicant offers that George also fails to teach the remaining components recited in claims 25 and 28.

The teachings of Soto do not remedy the deficiencies in George. Soto teaches a composition that comprises 100 parts olive oil and 10 parts beeswax. In other words, Soto teaches a 10:1 ratio of olive oil to beeswax. In contrast, the compositions recited in independent claims 1, 25, and 28 have, at most, about a 5:1 ratio of olive oil to beeswax. Even though Soto teaches two of the components recited in independent claims 1, 25, and 28, viz., olive oil and beeswax, Applicant offers that Soto, like George, fails to teach the remaining components recited in claims 1, 25, and 28.

For the reasons set forth on pages 4 and 5 of the Office Action, the Examiner is of the opinion that Ahrens, Kaplan, and Slimak teach the rest of the components of the claimed compositions, viz., sunflower oil, almond oil, and vitamins A, D, and E. Even if that were true, for at least the reasons set forth above, George, alone or in combination with

Soto, Ahrens, Kaplan, and Slimak, does not teach all of the claim limitations of independent claims 1, 25, and 28. And, aside from the conclusory statements¹ that the Examiner provides on page 6 of the Office Action as to why the claims are allegedly obvious over the art of record, the Examiner has not provided factual and objective evidence found in the prior art, that would cause the skilled artisan to combine the cited references to arrive at the claimed invention. *See, In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). *See also, In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references).

For the same reasons set forth above for claims 1, 25, and 28, George, alone or in combination with Soto, Ahrens, Kaplan, Slimak, and Martin (for claim 23), does not render obvious the claims that depend from claims 1, 25, and 28. Accordingly, Applicant asserts that the Examiner has failed to establish a *prima facie* case of obviousness against claims 1, 2, 5 - 15, 17, and 23 - 27. Reconsideration and withdrawal of the rejection are respectfully requested.

¹ For example, contrary to the Examiner's assertion on page 6 of the Office Action, not all references are directed to burn skin treatment compositions. Kaplan, in fact, is directed to a sun screen—a way to prevent burnt skin.

E. Oath/Declaration

Applicant filed a Declaration on December 5, 2005.

Applicant's attorney at the time inadvertently and unintentionally represented to the Patent Office that the Sencil preparation used in the human clinical trials consisted of from about 18 to about 27 percent by weight of beeswax; an oleaginous base of about 5% by weight olive oil, about 21% by weight sunflower oil, about 21% by weight almond oil, about 10% by weight cod liver oil, about 3% by weight castor oil; an added vitamin selected from the group consisting of vitamin A, D and E; a pharmaceutically acceptable excipient and a preservative. The undersigned has since learned that the Sencil preparation used in the human clinical trials is the one described in Exhibit A. That Sencil preparation comprises 12% beeswax, 6.253% olive oil, 15% sunflower oil, 9% almond oil, 5.228% castor oil, and 14.746% cod liver oil.

In view of the above, it is believed that this application is now in condition for allowance, and a Notice thereof is respectfully requested.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3620. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

/Ricardo J. Moran/
Attorney for Applicants
Ricardo J. Moran
Registration No. 48,735

PATENT ADMINISTRATOR
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Washington, D.C. 20007-5201



EXHIBIT A

Washington, DC.
April 24, 2007

Katten Muchin Rosenman LLP
Attn. Ricardo Moran
VIA FAXIMIL AND EMAIL

Dear Mr. Moran:

As discussed on the phone with regard to the patenting of our product "SENCIL" I wish to advise as follows.

The first offer for domestic sale of Sencil Hemorrhoids was May 2002 as an Over the Counter product.

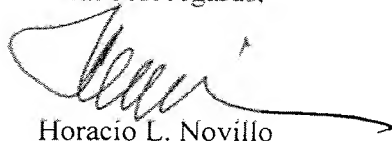
The composition of the product contained among others, the following raw materials:

- | | |
|-----------------|----------|
| - Beeswax | 12 % |
| - Olive Oil | 6.253 % |
| - Sunflower Oil | 15 % |
| - Almond Oil | 9 % |
| - Castor Oil | 5.228 % |
| - Cod Liver Oil | 14.746 % |

Please find attached a copy of a batch manufacturing procedure from Apex International, of Chaska, MN. where the product was manufactured.

Should you need additional information please do not hesitate and contact me.

With best regards,



Horacio L. Novillo
President & CEO

EXHIBIT B

Apex International Manufacturing Procedure

Product: Curacid, Sencil Proctology Ointment (For Export Only)

Formula # 100609

Effective Date: 1/10/2005

Revision #: 3

Reason for Revision: Replace Ruger Chemicals with "Apex" chemicals (CO 1266)

Prepared by: PJ Jirsa

Batch Size: 830 pounds

START UP CHECK LIST:

- 1 Read and be familiar with the Material Safety Data Sheet for all raw materials used in
- 2 this product. Wear appropriate safety equipment as required (safety glasses & protective gloves).
- 3
- 4 Make sure that all raw materials are pre-weighed according to Apex pre-weigh requirements.
- 5
- 6 Double check that all pre-weighed raw materials for this product are present before beginning batch mixing.
- 7
- 8 Make sure all cleaning and sanitizing procedures have been followed and documented.
- 9
- 10 Notify department manager before start up if any discrepancies are identified.
- 11

Procedure	Done by:	Date:	Time:
General Pre - Batching Instructions:			
Product Storage MUST Be In CLEAN Stainless Steel Drums and/or enameled drums			
Use stainless steel and/or enameled drums only in the transfer of product.			
Use a portable stainless steel cart for piping and equipment while setting up batches by the tanks.			
Verify that piping and equipment has not touched the floor. If so, re-sanitize equipment.			
Inspect rubber piping seals for damage and replace if required.			
Safety Glasses and Rubber Gloves are to be used whenever handling raw materials or product.			
Main Tank Characteristics:			
Stainless Steel tank with adjustable speed mixer.			
Tank with heating/cooling capability.			
Manually controlled steam and cold water (tap) valves.			
Bottom-drain.			
Recirculating Pump (set up to recirculate product under the surface).			
PROCEDURE:			
Add the following materials to the process tank:			
(SN: 000980) Olive Oil (Refined) Qty 51.9 pounds			
(SN: 000289) Sunflower Oil Qty 124.5 pounds			
(SN: 000647) Almond Oil, Sweet Qty 74.7 pounds			
(SN: 000659) Castor Oil AA Grade USP Qty 43.4 pounds			
(SN: 000334) Beeswax, Refined Yellow SP420 Qty 99.6 pounds			
(SN: 000321) Stearic Acid Qty 10.4 pounds			
Begin heating the batch to 65 - 70 C.			
Begin mixing when the batch is at least half-melted.			
Mix the batch at 65 - 70 C until all of the waxes have dissolved.			
Heating Time Started: Heating Time Completed:			
When the batch is homogeneous, add the following.			
(SN: 000620) Tenox BHT Qty 0.17 pounds			
Mix the batch for 15 minutes at 65 - 70 C to ensure that all of the BHT dissolves.			
Mixing Time Started: Mixing Time Completed:			

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46 When the batch is homogeneous, take a sample to be used by QC as an analytical blank,
47 continue to maintain the batch temperature at **65 - 70 C** for the addition of the Petrolatum.

49	(SN: 001026) Cod Liver Oil USP #0127-0	Qty	122.4 pounds
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50	(SN: 000580) Petrolatum, Snow White	Qty	303.0 pounds
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51 If using a tank with a valve assembly, attach a recirculating hose to the pump to ensure
52 that all of the solids dissolve. Begin re-circulation.

53 When all of the Petrolatum has melted and the batch is homogeneous, continue mixing
54 the batch for **30 minutes**. **NOTE:** Do not allow the batch temperature to go below **58 C**.

55 **Mixing Time Started:** _____ **Mixing Time Completed:** _____

56 For transfer to drums, make sure that the temperature of the batch remains at 58 C or
57 above (not to exceed 70 C).

58 Submit one set of **top and bottom** bulk samples to QC Lab for testing.

59 Submit **one sample** in a sterile cup to micro for bulk micro plating.

60 Stop recirculation only long enough to set up for transfer of product as described in
61 the next step.

62 Time Recirculation Shut Off :

63 Immediately, pump batch into stainless steel storage drums and/or enamel-coated
64 drums through a stainless steel **60 mesh** filter and cover with plastic wrap and
65 sealed lids. (**NOTE:** Do NOT use poly-lined drums)

830.0

Compounder Signature:

Date:

Research & Development Chemist

Date:

Quality Control Chemist: _____

Date:

Director of Laboratories & Q.C

Date: _____

Compounder Manager:

Date:

Customer: _____

Date: